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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,365	01/15/2004	Dean G. Karahalios	31132.141	5308
46333	7590	04/05/2006	EXAMINER	
HAYNES AND BOONE, LLP			REIMERS, ANNETTE R	
901 MAIN ST			ART UNIT	
SUITE 3100			PAPER NUMBER	
DALLAS, TX 75202			3733	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,365

Applicant(s)

KARAHALIOS, DEAN G.

Examiner

Annette R. Reimers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 12-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Rabbe et al. (U.S. Patent Number 5,702,453).

Rabbe et al. discloses various embodiments of a vertebral implant comprising a biologic strut/tubular body, 21, sized to fit between two vertebral endplates, a pair of ring-shaped, furrowed cleat assemblies, 22, each cleat comprising an outer end wall, an inner end wall, and a side wall which defines a hollow bore, wherein spikes, 91 or 120, extend from each outer end wall, and wherein each hollow bore is sized to fit over an end of the tubular body and slidably pass from the end along at least a portion of the length of the tubular body (see Figures 3 and 7 and column 7, lines 38-43 and 66-67 and column 8, lines 1-8). Furthermore, prior to interposition between the two vertebral endplates, the tubular body is slidably passed through the hollow bores in each of the cleat assemblies, and wherein the spikes on each outer end wall are directed away from each other and extend toward the opposite ends of the tubular body without extending past the opposite ends of the tubular body (see Figures 3 and 7 and column 7, lines 38-43 and 66-67 and column 8, lines 1-8).

The vertebral implant comprises an attachment assembly for attaching the tubular body to the cleat assemblies, comprising threaded apertures extending through the side walls of each of the cleat assemblies and a set screw, 24, attachment member extendable through the apertures into contact with the tubular body, wherein the set screws are extended through each of the threaded apertures after a distracting force varies the space between vertebral endplates to create the desired vertebral alignment (see column 8, lines 13-28). Openings, sized to permit graft material entry into the hollow bore, extend through the side walls of each of the cleat assemblies (see column 3, lines 42-45 and column 4, lines 55-57). The inner end wall of each of the cleat assemblies is provided with alignment positions for aligning and positioning the cleat assemblies and the outer end wall of the cleat assemblies is angled with respect to the inner end wall (see Figures 3, 9 and 10).

With regard to the statement of intended use and other functional statements, e.g. "slidably pass from the end along at least a portion of the length of the tubular body" they do not impose any structural limitations on the claims distinguishable over Rabbe et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not

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differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Regarding claims 21-24, the method for inserting a vertebral implant between two vertebral endplates is performed using the Rabbe et al. device (column 7, lines 38-43 and 66-67, column 8, lines 1-8, column 9, lines 36-67, and column 10, lines 1-12). Incidentally, it appears that there is a typographical error in the Rabbe et al. patent. Specifically, in column 7, lines 41-42, "each of the end caps" should be "each of the endplates", since the end caps, i.e. 23 do not have any threading. Therefore, logically the inventor is referring to the endplates, i.e. 22. This same error occurs again in column 8, lines 4-5. The internal threads, i.e. 41, are found on the endplates, i.e. 22, not on the end caps, i.e. 23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al. (U.S. Patent Number 5,702,453).

Rabbe et al. disclose the claimed invention except for the hollow bore of each cleat assembly being smooth. It would have been an obvious matter of design choice to construct the device of Rabbe et al. having the hollow bore of each cleat assembly

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being smooth, since applicant has not disclosed that having the hollow bore of each cleat assembly being smooth solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the hollow bore of each cleat assembly not being smooth.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al. (U.S. Patent Number 5,702,453).

Rabbe et al. disclose the claimed invention except the hollow bore having a diameter between 13mm and 25mm and the angle between the outer end wall and the inner end wall being between 4 and 15 degrees. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device of Rabbe et al. with the hollow bore having a diameter between 13mm and 25mm and the angle between the outer end wall and the inner end wall being between 4 and 15 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed on November 14, 2005 have been fully considered, but they are not persuasive. Examiner respectfully disagrees with applicant's argument that Rabbe et al. does not disclose "wherein each hollow bore is sized to ... "slidably pass from the end along at least a portion of the length of the tubular body", since Rabbe et al. does disclose "wherein each hollow bore is sized to ... "slidably pass from the end along at least a portion of the length of the tubular body." (see column 7, lines

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38-43 and 66-67 and column 8, lines 1-8). As previously stated, it appears that there is a typographical error in the Rabbe et al. patent. Specifically, in column 7, lines 41-42, "each of the end caps" should be "each of the endplates", since the end caps, i.e. 23 do not have any threading. Therefore, logically the inventor is referring to the endplates, i.e. 22. This same error occurs again in column 8, lines 4-5. The internal threads, i.e. 41, are found on the endplates, i.e. 22, not on the end caps, i.e. 23.

Furthermore, with regard to the statement of intended use and other functional statements, e.g. "slidably pass from the end along at least a portion of the length of the tubular body" they do not impose any structural limitations on the claims distinguishable over Rabbe et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In addition, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Moreover, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). In addition, the limitations on which the Applicant relies (i.e., "slidably passing" is meant to mean axial movement without heavy threaded retention) are not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not.

Examiner respectfully disagrees with applicant regarding the method for inserting a vertebral implant between two vertebral endplates, i.e. claims 21-24. Applicant states

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that Rabbe et al. fails to disclose "sliding the cleat assemblies over the tubular body." However, Rabbe et al. does disclose "sliding the cleat assemblies over the tubular body" (see column 7, lines 38-43 and 66-67 and column 8, lines 1-8). As previously stated, it appears that there is a typographical error in the Rabbe et al. patent. Specifically, in column 7, lines 41-42, "each of the end caps" should be "each of the endplates", since the end caps, i.e. 23 do not have any threading. Therefore, logically the inventor is referring to the endplates, i.e. 22. This same error occurs again in column 8, lines 4-5. The internal threads, i.e. 41, are found on the endplates, i.e. 22, not on the end caps, i.e. 23.

In addition, examiner respectfully disagrees with applicant regarding Rabbe et al. lacking the steps of "interposing a distraction device between the cleat assemblies; applying a distraction force with the distracting device whereby at least one of the cleat assemblies is moved into engagement with at least one of the vertebral endplates." Rabbe et al. discloses "interposing a distraction device, 105, between the cleat assemblies; applying a distraction force with the distracting device whereby at least one of the cleat assemblies is moved into engagement with at least one of the vertebral endplates." (see figure 9 and column 9, lines 36-67, and column 10, lines 1-12).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER